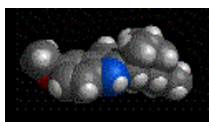


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The purpose of this document is to provide information. Treatment providers and patients are solely responsible for their actions.

Manual for Ibogaine Therapy

Screening, Safety, Monitoring & Aftercare

Second Revision

by

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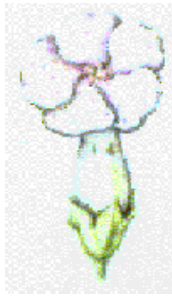
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The Ibogaine Dossier

The Second Revision of the Ibogaine Manual follows a year and a half after the publication of the First Revision providing new information to the field.

This revision of the manual offers additional information on ibogaine therapy as well as, differing philosophies of ibogaine providers and their approaches to therapy. There is consensus as to the benefits of post ibogaine therapy but, no agreement that any one therapy offers benefits over others to a majority of subjects. Many authors feel the exclusion criteria indicated in the draft protocol of the National Institute on Drug Abuse (NIDA) are not realistic to allow treatment of today's chemically dependent drug users who may be depressed or display other psychiatric disorders nor does it allow for the prevalence of HCV and/or HIV to allow those individuals to be treated with ibogaine. The authors review broader ibogaine dose regimens and their advantage than were presented in the First Revision of this manual. The new material is principally found in the Discussion Section that may be referenced from the links of the Table of Contents above though some changes and corrections have been made throughout the text as a whole. Opinions of authors remain diverse.

Links to a [medical encyclopedia](#) as well as, both the home edition and Centennial/Professional edition of the [Merck Manual](#) are included in the Additional Documents section. "The Merck Manual, the textbook of medicine most widely used by health care professionals provides vital information about diseases, diagnosis, prevention, and treatment." The Ibogaine Manual now also contains a link to a redacted version of the Diagnostic and Statistical Manual of Mental Disorders (DSM IV) to allow better understanding of mental disorders that may be concurrently seen in persons who are chemically dependent.

Though the Internet allows rapid publication it also has a component of rapid disintegration with web pages linked to the manual being withdrawn from the web by original authors. Therefore the authors of this manual have included where possible multiple links to any particular subject in the appendices so as to maintain information access for the reader.

All links that will take the reader outside of the Ibogaine Manual will highlight on mouseover with most but, not all browsers. These links are found only in the Additional Document section. Links that will take the reader outside of the Ibogaine Dossier web page will appear in separate windows with the Manual remaining visible in the background.

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Preface

Ibogaine therapy has emerged in the last twenty years as a viable option for motivated chemically dependent individuals who wish to cease their dependence. The extremely costly

regulatory approval process and the reluctance by major pharmaceutical firms to pursue regulatory approval in the West has led to the formation of non-medical ibogaine treatment movements in many countries. This document is intended for medical doctors as well as, for lay-healers who have little or no medical experience, but who are nevertheless concerned with patient safety and the outcome of Ibogaine treatments. The NIDA draft clinical protocol, however, may be useful to researchers in formal drug development.

It is the responsibility of those treatment providers to safely conduct the procedure despite possible limitations of clinical knowledge, patient compliance, money, time etc. The safety of Ibogaine treated patients is the primary objective of this document. Reported Ibogaine-related problems or fatalities might very likely be avoided if simple screening, dosing and monitoring guidelines are adhered to. However, this must be taken in some context as, in 1999 there were 116,000 drug related fatalities in United States hospitals associated with FDA approved medications.

This manual includes selected portions of the National Institute on Drug Abuse (NIDA) Draft Ibogaine Clinical Protocol obtained under a Freedom of Information Act (FOIA) request. Selections are principally directed towards safety issues. Aspects of the therapeutic sessions from the NIDA protocol are included as well as, bibliographical citations relevant to the sections from the protocol. More recent reports providing updated information are included in the Additional Documents section.

Any comments of the author(s) within the selected protocol text are indicated by "[]" brackets. The "*" asterisk is used to indicate tests procedures or surveys not included in NIDA's 1993, draft protocol but, suggested either in discussion with the FDA or by later publication.

In a memorandum dated March 10, 1995, Dr. Curtis Wright, Medical Review Officer, Pilot Drug Evaluation Unit, FDA wrote, "I think that ibogaine research will be propelled forward by its advocates, as it will be very hard to make a case that it is unsafe to take a drug into man when there is such substantial documented human experience. I agree with the speaker [March 1995, NIDA Ibogaine Review Meeting] that it is a risk-benefit analysis, but all such development decisions are finally reduced to this basis. The Development question is if ibogaine can be given safely, and if so, will it provide some benefit."

Ibogaine has been propelled by its advocates since then, and administered in many countries often outside the medical establishment. Unfortunately, safety issues are not frequently addressed or evaluated properly. Our objective is to provide basic guidelines and improve patient safety with information. This information is made available for the benefit of the treatment provider and their patients.

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Treatment

Intake and Safety Issues

Needless to say, it is evident that most persons outside of a research institution would not be able to undertake the testing presented in the NIDA ibogaine protocol. The primary issue the authors are attempting to address is that no medical testing is the norm for many persons receiving ibogaine therapy. This leaves both providers and patients at risk. Risk cannot be eliminated but, as inferred by Dr. Curtis Wright in the introduction to this article, risks must be weighed against benefits. It is apparent from the actions of both ibogaine providers and chemically dependent persons who seek treatment that the benefits are significant. However, with no less than three documented ibogaine-related fatalities, so are the risks. Having safety procedures in effect are not for the benefit of the majority of the patients who will go through ibogaine therapy with no problems but, to assure the survival of a small minority of the patients who may experience some form of adverse medical event that may be life threatening.

One of the recorded fatalities was reported to have taken place in 1989 in France. The patient, a

forty year old woman was provided a dose of 8 mg/kg of purified ibogaine for purposes of psychotherapy from which she died approximately four hours after administration of ibogaine. The dose given was the lowest dose associated with an ibogaine related fatality that has been recorded and the autopsy found significant blockage of the main arteries to the heart. It was indicated that the patient had a history of cardiovascular disorders that may not have been investigated. This immediately indicates two areas that should be given priority attention by ibogaine providers: 1) A medical history and 2) an electrocardiogram (EKG).

The most common form of a medical history is usually a questionnaire required of every patient visiting a doctor for the first time and your doctor's office is an excellent source of such a document. Among the information required on such forms are issues relating to heart disease and these questions if honestly answered will provide an alert to the existence of a cardiac disorder. As, previously stipulated because medical conditions may not be known to the patient an electrocardiogram (EKG) should be included in any basic intake for ibogaine therapy. Information on electrocardiograms can be found in [documents #6 and #7](#). Any history of heart attacks should be a reason not to treat a patient with ibogaine.

Whether in a hospital or outside of a medical environment the patient's safety can be best provided for by continuously observing the patient. A nursing assistant or other trained person should observe the patient continuously for 48 hours or longer if the patient response to ibogaine requires it. During this period pulse and blood pressure should be monitored at regular intervals and at any time that patients indicate discomfort or the observer has concern. The regular intervals may be as short as 30 minutes for the first four hours or until blood pressure and pulse are stable and then at time points of 1 hour to 4 hours thereafter.

Observers should have training in cardiopulmonary resuscitation and be prepared to call a hospital or emergency medical services should the patient's pulse drop below 50 beats per minute. If you are not prepared to call for emergency medical help you should not be providing ibogaine therapy. A hospital should be called at any time if a patient loses consciousness. The emergency number to be called should be available to all provider personnel at all times. Observing the patient is more work than one person can realistically accomplish. In a hospital setting nursing staff would normally rotate on 8 to 12 hour shifts.

The evaluation of blood chemistry is a standard means of assessing the health of a patient and is often used in medical evaluations of patients during annual physicals or to determine the health of a patient at any time for any purpose. The SMA-20 (a series of tests to evaluate blood chemistry) along with a CBC (complete blood count) with differential now appear to be the tools of choice to provide a wide range of information relating to blood chemistry that includes a liver profile but, does not include a hepatitis or HIV screen. Excellent resources concerning the SMA-20, CBC and definitions to allow an understanding of the associated terminology can be found in [#3, #4, and #5](#) of the document section.

The second recorded fatality was that of a woman in her mid twenties in the Netherlands who received 29 mg/kg in a split dose of 23 mg/kg and an additional 6 mg/kg approximately 3 hours later. The patient died 16 hours after the administration of ibogaine. The autopsy did not determine the cause of death. The unanswered question of the cause of death brings us to another important safety issue. Ibogaine has been shown to increase the effects of opiates as well as opiate toxicity. Ibogaine may also increase the potency and toxicity of stimulants. Therefore patients should be warned that concurrent drug use during ibogaine therapy may be fatal. It does not mean that concurrent drug use will always be fatal as an early report of an ibogaine experience, [Reflections on an Ibogaine Experience](#) found in document #8 of this manual indicates concurrent heroin use that did not result in a fatality. It must be recognized that the response to drugs is individual and that each patient may present a dramatic or not so dramatic distinction in how they respond to ibogaine or other drugs. Ibogaine providers should attempt to minimize danger to the patient by eliminating the use of unauthorized drugs by the patient while under the influence of ibogaine. Good luck on that matter in circumstance where you are treating experienced and dependent drug users. This is why it is very important to let the patient know that drug interaction may be fatal.

The third fatality of record occurred in 2000, in the UK. The patient was a 38 year old male who was administered a total of 5 or 6 grams of a 15% total iboga alkaloid extract over a period of six hours. The patient appeared fully recovered, had eaten breakfast, gone to the toilet and suddenly died approximately 38 hours after the administration of the plant extract. The patient had hepatitis C but, exact data on the state of the disease is not available. The subject had been using heroin for 15 years. The most troubling issue relating to this fatality is that it occurred after the apparent recovery of the subject and quite suddenly. The extract has been widely used and there appears to be no greater fatality-related issues associated to it than to purified ibogaine.

NIDA in its draft protocol and the FDA in the protocol it approved in 1993, excluded patients with hepatitis C. One of the authors believes this was not so much a safety issue but, one that would allow a determination of the transformation of ibogaine into its metabolites by the liver and the associated plasma levels to be validated in pharmacokinetic studies within ranges that would be normal and not to have them skewed by a diseased liver. It is reported that the St. Kitts facility excludes HCV and HIV patients. NDA International, Inc. in its work in The Netherlands and Panama accepted HCV and HIV that were not symptomatic for the diseases. As many chemically dependent drug users test positive for HCV and as there has been no known correlation of fatalities with HCV, it does not seem that this is a reasonable exclusion criteria in the real world of chemical dependence. Non-symptomatic HIV patients have also been treated without apparent medical events. NIDA chose to exclude patients with liver enzyme values exceeding 400% above normal from a later study design. A decision to follow NIDA's footsteps on this matter may be reasonable until more information is available.

Ibogaine appears to be a very safe drug in terms of psychiatric events. One of the authors is aware of a single event from a report where a patient apparently regressed, acted in a childlike manner and urinated in bed for a period of two days, thereafter recovering. An early patient who had been hospitalized on a number of occasions for glue-sniffing related psychosis became paranoid during his first treatment and exhibited behavior distinct from any other ibogaine patient during a second treatment episode. Ibogaine providers should be aware that chemically dependent or not, many persons are going to come to them with underlying and in some cases significant underlying psychiatric disorders. NIDA's exclusion criteria for "patients with a history of active neurological or psychiatric disorders, such as cerebellar dysfunction, psychosis, bipolar illness, major depression, organic brain disease or dementia, that require treatment", may be well thought out and these patients should be avoided by persons not having professional skills in psychiatry and psychopharmacology. These matters are further reviewed in the Discussion section of this manual.

Anything that can be learned about the patient prior to treatment is valuable. And, anything learned before treatment will most likely allow a greater interpretation of events after treatment. To this end the [Beck Depression Inventory, document #9](#), linked in the Additional Documents Section may be valuable as may the Minnesota Multiphasic Personality Inventory-2 ([MMPI-2 document #10](#)). The tests are generally only available to persons who are professionally involved in psychology or testing who then provide them to patients. Once provided with a diagnoses it is necessary to understand those disorders. To that extent the Diagnostic and Statistical Manual of Mental Disorders, 4th. Edition, better known as the [DSM-IV, document #11](#) is published by the American Psychiatric Association is a standard in the field.

Taking this broad ranging discussion to a brief conclusion, every ibogaine patient should receive an SMA-20 and CBC blood test and an EKG. These discussions are made in the hope of initiating greater associations between non-medical ibogaine providers and medical professionals who can assist them in increasing the safety of ibogaine treated patients. Questions coming out of the London Ibogaine Conference held in December of 2001, concerned the required testing, how to obtain it and how to understand it. The International Coalition for Addict Self-Help (ICASH) in their work in the late 1980s and early 1990s faced the same problems. Their solution was to have the patient walk into an emergency room or community health service with a friend and to have the friend inform the staff that the person with them had a pain in the chest and passed out and when unconscious appeared to go into convulsions. This usually resulted in the patient obtaining a blood chemistry, an EKG and EEG to investigate the possibility of epilepsy and

cardiovascular disorders. ICASH would then obtain a written authorization to obtain the medical records from the patient and request the tests results and reports of the results from the hospital where the patient was evaluated indicating that the patient was to be included in a research program. The tests and reports were then usually reviewed by a doctor who had some interest in ibogaine therapy. In any case, with the basic medical testing accomplished there is at least a place to begin in offering safe ibogaine therapy. Patients who could afford to pay for testing and did not want to indicate their chemical dependence would inform a doctor that they were going on a trek in some physically taxing geographical location and that medical testing was required to participate.

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Dose and effect

After years of review of reports of hundreds of ibogaine patient treatments, the effective dose for the treatment of chemical dependence, including opioid dependence, has been seen to be between 15 mg/kg and 20 mg/kg of ibogaine. It has been reported by some researchers that lower doses are effective but, this has been disputed. Effects of ibogaine generally will make themselves evident within 45 minutes to as long as, three hours after administration. In most cases opioid withdrawal signs will be reduced within 45 minutes of ibogaine administration. Ibogaine is usually administered in place of what would be the next scheduled dose of narcotics. This would provide for an ibogaine administration schedule 8 hours after the last dose of heroin, morphine or demerol and 24 hours after the last dose of methadone. It is expected that the patient would be exhibiting minor withdrawal signs at the time of ibogaine administration. There is no experience with ibogaine in the treatment of LAAM dependence.

Another issue pursuant to dose is that of dose increases, should anticipated effects including the diminishment of opioid withdrawal not be seen. Modification upwards of ibogaine doses have been used occasionally within medical environments and commonly by some lay providers as well as, within the African religious context. The issues remain of ability to respond to medical emergencies and of the experience of the provider to determine the safety at any time of the patient. It may be prudent to allow the primary dose of ibogaine to run its course and then provide a second dose a week later if required. That is, if the patient is still chemically dependent or exhibiting drug craving?

Once ibogaine has been administered, effects follow. The patient will usually want to lay prone and should be encouraged to remain still as nausea and vomiting as well as, being systemic have been seen to be motion related. The skin tends to become numb. Patients will report an initial buzzing or oscillating sound. A period of dream-like visualization lasting for 3 to 4 hours in most but, not all patients is considered to be the first prominent stage of ibogaine effects. This stage ends abruptly should it occur at all. Another aspect of ibogaine effect that is common are random flashes of light that appear everywhere with eyes open. This may last for hours or days. Visualization on the other hand is most common with eyes closed.

The second stage that follows visualization has been described as one in which the subject principally experiences cognitive evaluation or a review of issues that are important to the subject. These may cover every possible scenario from early childhood experiences to current health issues. This period may last for as few as 8 hours or for 20 hours or longer.

The third or final stage of ibogaine effects is that of residual stimulation. This stage, because it tends to leave the subject/patient exhausted is somewhat uncomfortable. Subjects may remain awake for two or more days. Most patients will sleep within 48 hours of ibogaine administration. Some within 24 hours of administration. Usually, there is a long term long term diminishment of the need for sleep over weeks or months. Some patients may require or request sedation. Sedatives that have been used include benzodiazepines, barbiturates and melatonin.

The effects herein described are those of single administration high dose ibogaine regimens. Ibogaine has also been given in regimens of small daily doses of 25 mg to 300 mgs/day and in small daily doses where the dose is increased on a daily basis until the desired interruption of

drug dependence is accomplished. These low dose modalities have not been validated for efficacy to the same extent as have the full therapeutic doses of ibogaine. However, these low dose regimens can be traced back some decades to the work of Leo Zeff who in the case of a single patient provided ibogaine on an "as needed" basis via nasal administration to a cocaine dependent patient to substitute for his cocaine use. Lines of ibogaine were somewhat equivalent to lines of cocaine and the patient ceased cocaine use after a week of this daily self-regulated ibogaine regimen. Additionally, reports from Canadian sources indicate multi-week low dose ibogaine therapy 20 mg/day following a therapeutic dose of ibogaine in the treatment of cocaine dependence. Further, reports throughout the ibogaine provider community indicate the use of multiple dosing of varying strength doses over varying time periods in the treatment of opioid dependence. As with all determinations in medicine, decisions must be made on observations of the patient and knowledge of the disorder(s) and the medication(s) used.

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Opioid Withdrawal

An issue that all ibogaine providers treating opioid dependent patients will have to address is discomfort due to opioid withdrawal signs, real or imagined by the patient. To this end it may be helpful during a patient intake interview to ask what withdrawal signs the patient has had in previous withdrawal experiences. During ibogaine therapy this information will be more useful if the provider has had experience observing opiate withdrawal signs as well as, observing patients given ibogaine who were not opiate or chemically dependent. The reason being that certain effects of ibogaine may mimic opiate withdrawal. These signs may include inability to sleep, nausea, a feeling of being cold or vomiting. It is the skill of the provider that will enable the provider to determine whether withdrawal signs are real or imagined and to assist the patient in understanding the difference. It must be recognized that elimination of withdrawal signs are not necessarily isolated ends in themselves to heroin or other opioid dependent patients. Being sick is a rational justification for relief and the simple presentation by the patient that they are exhibiting opiate withdrawal to a significant other or peer or other person in their environment has probably been used by the patient to obtain opiates or the money to do so. The conditioned response of obtaining gratification and/or attention by exhibiting opioid withdrawal signs or claiming to exhibit opiate withdrawal signs has been a successful behavioral mechanism for some patients and should be expected. Generally, if the complaint of withdrawal is made it can be expected between the 14th and 24th hour of treatment and may continue through recovery from ibogaine effects.

Two useful surveys that should be included in ibogaine therapy are the Objective Opiate Withdrawal Scale (SOWS) and the Subjective Opiate Withdrawal Scale (SOWS). Examples of these diagnostic tools follow.

Objective Opiate Withdrawal Scale (OOWS)

Instructions: Rate the patient on the basis of what you observe during a timed 10-minute period.

Date: _____ Time: _____

ITEM	SCORE 1 POINT FOR EACH ITEM IF:	POINTS
Yawning	present	

Rhinorrhea	3 or more	
Piloerection (observe pt's arm or chest)	present	
Lacrimation	present	
Mydriasis	present	
Tremors (hands)	present	
Hot flashes	present	
Cold flashes (shivering or huddling for warmth)	present	
Restlessness	present	
Vomiting	present	
Muscle twitches	present	
Abdominal cramps (holding stomach)	present	
Anxiety (finger tapping, fidgeting, agitation)	present	
TOTAL OOWS SCORE (Sum items 1 - 13)		

Subjective Opiate Withdrawal Scale (SOWS)

Instructions: Answer the following statements as accurately as you can.

Circle the answer that best fits the way you feel now

Date: _____ **Time:** _____

(1 = Not at all) (2 = A little) (3 = Moderately) (4 = Quite a Bit) (5 = Extremely)					
I feel anxious	1	2	3	4	5
I feel like yawning	1	2	3	4	5
I'm perspiring	1	2	3	4	5
My nose is running	1	2	3	4	5
I have goose flesh	1	2	3	4	5
I am shaking	1	2	3	4	5
I have hot flashes	1	2	3	4	5
I have cold flashes	1	2	3	4	5
My bones and muscles ache	1	2	3	4	5

I feel restless	1	2	3	4	5
I feel nauseous	1	2	3	4	5
I feel like vomiting	1	2	3	4	5
My muscles twitch	1	2	3	4	5
I have cramps in my stomach	1	2	3	4	5
I feel like shooting up now	1	2	3	4	5

To assist in an understanding of the comparative effects of ibogaine and opioid withdrawal effects, the reader should review [Alper et al., #12](#) of the Additional Document section as well as, the findings from **Ibogaine in the Treatment of Narcotic Withdrawal** ([document #13](#)) by Lotsof, Della Sera and Kaplan presented during the 37th International Congress on Alcohol and Drug Dependence, University of California, San Diego, (1995). The relevant table from that paper is found below.

Objective Opiate Withdrawal Signs and Ibogaine Signs: Human Observations

Signs	Opiate Withdrawal	Ibogaine	Ibogaine + Opiates
Diarrhea	Yes	No	*3% - 12%, 6 days post
Yawning	Yes	Rare	Rare
Rhinorrhea	Yes	No	No
Piloerection	Yes	No	No
Lacrimation	Yes	No	No
Mydriasis	Yes	No	5% (moderate)
Shivering	Yes	No	No
Restlessness	Yes	Post 20 Hrs ibogaine	Post 20 Hrs ibogaine
Vomiting	Chronic	Acute/Motion related	Acute/Motion related
Muscle Twitches	Yes	No	No
Abdominal Cramps	Yes	No	No
Sweating	Yes	No	*16% - 25%
Anxiety	Yes	No	3%
Sleeplessness	Yes	Yes	Yes

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Post Ibogaine Treatment Therapy

The principal effects of ibogaine treatment that are reviewed in Lotsof's Clinical Perspectives ([document #14](#)), Frenken's An Ibogaine Treatment Protocol ([document #15](#)) and Sandberg's Introduction to Ibogaine ([document #16](#)) will usually run their course within two days. There are exceptions with some patients recovering in as little as 24 hours while others may require an additional day or even have to be coaxed out of bed four days after treatment. Thereafter, the patients are left with the rest of their lives to accomplish and with the majority of individuals needing some form of assistance to figure out how to go about moving forward. Some patients will have a fear of going into withdrawal. This is not a realistic expectation on their part. More realistic is the fear of relapse to drug use and except in rare instances this should be anticipated particularly after only the first treatment with ibogaine.

Addiction has been viewed as a chronic relapsing condition. Ibogaine's value is not only the interruption of withdrawal but, by mechanisms not fully understood to assist the patient in changing learned behavior and becoming more aware of their behavior in order to change it. After ibogaine therapy many patients become more agreeable to change. Thus, ibogaine provides a unique opportunity. The question to the ibogaine treatment community is how to best make use of that opportunity?

A fundamental question remains. Is any form of adjunct therapy to the administration of ibogaine more advantageous than any other form of post ibogaine treatment therapy? The question becomes more diverse where in the absence, in many cases of the possibility of additional treatment with ibogaine, opiate dependent patients who have relapsed have made good use of methadone maintenance as an effective intermittent therapy so that methadone must also be included in the mix of therapies that have been effectively used by ibogaine treated patients to eventually free themselves from addiction. Thus, we see patients making use of psychoanalysis, psychotherapy both individual and group of varieties as distinct as the persons who provide such therapies, methadone maintenance, and associations such as Narcotics Anonymous and Alcoholics Anonymous. What does appear evident is that contact with non-addicted persons is generally beneficial for patients and that continued contact with users of drugs that cause dependence is detrimental to a goal of abstinence if that is the endpoint desired. This is not distinct from the findings observed in non-ibogaine environments.

Many ibogaine patients themselves indicate that they have a need for and want some form of therapy or support. The issues become more complex in patients whose long term addiction has left them without the skills or education to function outside of a drug user context. Providing ibogaine is a relatively easy short term goal. The time needed to heal patients of trauma they have experienced and to address deficits in the patient's life is more time consuming and a more long term goal. In many cases the patient's lack of financial ability to obtain assistance for therapy, education or occupational training will require societal assets or private donations to be made available.

Only recently have agencies such as the Center for Substance Abuse Treatment and the National Institute on Drug Abuse in the United States recognized that the prejudice shown towards drug users is harmful in itself and detrimental to patients seeking treatment. A growing number of individuals question whether prohibition is the greatest harm of all while a greater number of persons are calling for a harm reduction philosophy wherein the minimalization of the level of harm to drug users and society is viewed as a priority over any immediate requirement of abstinence.

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Discussion

OVERVIEW

The Second Revision of the Manual for Ibogaine Therapy continues to focus on safety issues while expanding the discussion of dose regimen and forms of ibogaine that include purified forms of the chemical as well as, total alkaloid extracts of varying strengths. These matter are important as ibogaine treatments are taking place in a growing number of countries and under diverse circumstances. Some ibogaine providers in research facilities provide testing as complex as that indicated in the National Institute on Drug Abuse (NIDA) ibogaine protocol. Others in non-medical environments, apartments, hotels or chapels may not include any medical testing at all. This Discussion Section contains viewpoints of all of the authors.

One author in addressing the safety issues of ibogaine states, "The drug is dangerous and shouldn't be compared to other tryptamines. People definitely have died and there may be more fatalities unrecorded. You need to check liver and heart and be able to assess the results. You need to know resuscitation procedures and be prepared to call emergency medical assistance if necessary." These statements bring us to central issues: key tests and the ability to understand them. While the authors recognize that virtually every drug product may have associated fatal reactions, the issue with ibogaine is, as it is with all drugs, that the responsibility is not only that of the patient/subject but, that of the provider. That alone should be reason for providers to screen for indicated health disorders.

Safety evaluations may be viewed in terms of an optimal screening/testing protocol and a non-optimal screening/testing protocol. The optimal being as complete and far reaching as possible including medical history, laboratory tests, evaluations by physicians as to general, neurological and psychological health including a broad range of questionnaires to allow such determinations. An excellent questionnaire to begin a structured case history on patients can be found in the the Guidelines for Psychiatric Evaluations of Adults, [document #17](#). Instruments to assist in assessments can be found in The Catalogue of Diagnostic Questionnaires, [document #18](#) and the Brief Psychiatric Rating Scale, [document #19](#). Non-optimal testing would include the bare necessities to investigate areas of medical concern that have been raised in ibogaine literature. These include cardiovascular, metabolic and absorption concerns. Additionally, reports from ibogaine treatment observations also indicate respiratory depression may be an issue as one patient was reported to have stopped breathing before then being revived.

It should be noted that female subjects might be more sensitive to ibogaine due to higher blood levels of ibogaine and/or its principal metabolite (noribogaine) than are seen in male subjects. One, of an excellent series of articles published in The Scientist, The Inequality of Drug Metabolism, concerns itself with this matter, [document #20](#). While absorption and metabolism factors are not distinct to ibogaine and are common to many drugs, individual patient responses to dose and particularly sensitivity of females to ibogaine must be recognized. Obviously, further research is required and the authors request the participation of ibogaine providers to supply relevant reports and data for future revisions of this manual. The FDA in their approval of ibogaine clinical studies in 1993, excluded women. This was in conflict with Institute of Medicine (IOM/United States) guidelines that indicate women should be included in the earliest research testing of drugs. The pharmaceutical industry, principally for issues of liability and cost, tests new drugs only on men in the majority of early clinical studies.

While the drug metabolism for ibogaine and for many pharmaceutical products may be better understood for distinctions between men and women, there is still no fundamental agreement on the responses of men and women to ibogaine. Wells in her very well thought out article, Notes for Treatment Providers, [document #21](#), finds that women appear less responsive and more problematic as patients while Lotsof in his work finds women to be more responsive and less problematic as ibogaine patients. Hopefully, as more people are treated we will see a greater statistical understanding of the patient population.

One author suggests that medical testing should not be included when ibogaine is used as a religious sacrament and that under those conditions a religious exemption to medical testing should be considered valid. The author indicates that persons undergoing religious initiation are

questioned at length to their health and not only are they questioned but, those who will accompany them during the initiation are also questioned and advised as to the possibility of death. The author indicates that once the possibility of fatalities are mentioned that usually more significant information is provided as to the health of the initiate. The author also indicates that women initiates are informed they may be at greater risk and are asked should they find the door that allows them to leave this life that they must not take that door as it would be destructive for everyone involved. These descriptions appear to be in keeping with the protocol or rites used within the African Bwiti initiations.

The primary question the authors must address is who may be administered ibogaine?

To that end we must present inclusion criteria for ibogaine therapy or initiation. The terms "therapy" and "initiation" are used, as ibogaine is available in paradigms that include religious initiation, treatment for chemical dependence and administration for psychotherapeutic or "exploratory" purposes.

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INCLUSION CRITERIA

"Testing for sexually transmitted diseases is always important in the chemically dependent population," states an author, "so I would also include VDRL to test for syphilis."

1. Subject participation must be voluntary and not coerced.
2. Subject must sign an Informed Consent that indicates and understanding of the risks and benefits of ibogaine administration.
3. Subject must undergo a general medical evaluation by a doctor who will provide a report.
4. Subject must supply a copy of their medical history questionnaire (generally required upon the intake visit to a physician).
5. Subject must respond to a Beck Depression Inventory questionnaire.
6. Subject must obtain an EKG (electrocardiogram) and report.
7. Blood tests including:

- * albumin: 3.9 to 5.0 mg/dl
- * alkaline phosphatase: 44 to 147 IU/L
- * ALT (SGPT): 6 to 59 IU/L
- * AST (SGOT): 10 to 34 IU/L
- * BUN: 7 to 20 mg/dl
- * calcium - serum: 8.5 to 10.9 mg/dl
- * serum chloride: 101 to 111 mmol/L
- * CO₂: 20 to 29 mmol/L
- * creatinine: 0.8 to 1.4 mg/dl
- * direct bilirubin: 0.0 to 0.3 mg/dl
- * gamma-GT: 0 to 51 IU/L
- * glucose test: 64 to 128 mg/dl
- * phosphorus - serum: 2.4 to 4.1 mg/dl
- * potassium test: 3.7 to 5.2 mEq/L
- * serum sodium: 136 to 144 mEq/L
- * total bilirubin: 0.2 to 1.9 mg/dl
- * total protein: 6.3 to 7.9 g/dl
- * uric acid: 4.1 to 8.8 mg/dl

- * RBC (varies with altitude): (male: 4.7 to 6.1 million cells/mcl) (female: 4.2 to 5.4 million cells/mcl)
- * WBC 4,500 to 10,000 cells/mcl

- * **hematocrit** (varies with altitude): (male: 40.7 to 50.3 %) (female: 36.1 to 44.3 %)
- * **hemoglobin** (varies with altitude): (male: 13.8 to 17.2 gm/dl) (female: 12.1 to 15.1 gm/dl)

8. Upon subject meeting all other inclusion criteria and not being excluded by exclusion criteria, subject will be administered a 100 mg (total) test dose of ibogaine. Should the subject not have an adverse or atypical response, a full therapeutic dose of ibogaine may be considered. See exclusion criteria #4.

9. Ibogaine providers following a medical model may require evaluation of cytochrome P450 enzymes activity. Particularly, P450 2D6 (CYP4502D6) plays a significant role in the metabolism of ibogaine to noribogaine, its active metabolite. Testing allows a determination of whether the patient will be a "poor metabolizer" (PM), "intermediate metabolizer (IM), extensive metabolizer (EM) or "ultra rapid" metabolizer (UM). This testing is now available through commercial laboratories.

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EXCLUSION CRITERIA

In order to begin to address the safety of persons being treated with ibogaine, the following indications should exclude treatment with ibogaine. A discussion of these matters by various authors follow the list below.

- 1.** Patients with a history of active neurological or psychiatric disorders, such as cerebellar dysfunction, psychosis, bipolar illness, major depression, organic brain disease or dementia, that require treatment.
- 2.** Patients who have a Beck Depression Inventory score greater than or equal to twenty-four.
- 3.** Patients requiring concomitant medications that may cause adverse ibogaine/other drug interactions (e.g., anti-epileptic drugs, antidepressants, neuroleptics, etc.)
- 4.** Patients with a history of sensitivity or adverse reactions to the treatment medication.
- 5.** Patients with a history of significant heart disease or a history of myocardial infarction.
- 6.** Patients with blood pressure above 170 mm Hg systolic/105 mm Hg diastolic or below 80 mm Hg systolic/60 mm Hg diastolic or a pulse greater than 120 beats per minute or less than 50 beats per minute.
- 7.** Patients who have a history of hypertension uncontrolled by conventional medical therapy.
- 8.** Patients who have received any drug known to have a well-defined potential for toxicity to a major organ system within the month prior to entering the study.
- 9.** Patients who have clinically significant laboratory values outside the limits thus specified by normal laboratory parameters.
- 10.** Patients who have any disease of the gastrointestinal system, liver or kidneys, or abnormal condition which compromises a function of these systems and could result in a possibility of altered metabolism or excretion of ibogaine will be excluded. As it is not possible to enumerate the many conditions that might impair absorption, metabolism or excretion, the provider should be guided by evidence such as:
 - A.** History of major gastrointestinal tract surgery (e.g., gastrectomy, gastrostomy, bowel resections., etc.) or a history or diagnosis of an active peptic ulcer or chronic disease of the gastrointestinal tract, (e.g. ulcerative colitis, regional enteritis, Crohn's disease or gastrointestinal bleeding).

B. Indication of impaired liver function.

C. Indication of impaired renal function.

11. Patients with active tuberculosis.

12. Pregnancy

"Regarding the manual I would disagree with some of the exclusion criteria," says one author. "By excluding patients that are depressed or bipolar you exclude a sizable portion of the addict population. Because ibogaine's metabolites have been shown to have an antidepressant effect it would probably help these patients. Proper treatment for psychiatric conditions can be administered afterward. You will find below some of the experience we have had with patients taking antidepressants prior to ibogaine and since many patients have psychiatric conditions, we don't consider it prudent or necessary to suspend psychotropics for longer than 24 hours before treatment. Below are presented three examples of such patients. All of these patients suspended their medications 24 hours prior to treatment and apparently had no different responses to ibogaine or any unexpected side effects."

- | |
|--|
| <ol style="list-style-type: none">1) 22 year old male on Prozac (fluoxetine) 20 mg for 14 months.2) 38 year old male on Zoloft (sertraline) 100 mg for 2 years.3) 36 year old female on Paxil (paroxetine) 40 mg for 1 year. |
|--|

"Since most patients are depressed, a fast acting antidepressant can help in the days after ibogaine. We have found S-adenosyl-L-methionine (SAME) to be useful. If necessary we also prescribe SSRI's. These take about two weeks to start working. Another simple but effective therapy is DHA (omega-3 fatty acids). These reduce depression and stabilize mood."

Commenting on the exclusion criteria, another author states, "I don't think depression should be taken as a contraindication. I've treated a lady with an extreme depression hoping it would help. It didn't. The condition remained unchanged. Of course, one case - no case. People on Oxycontin often claim depression. No wonder - that's what the interruption of oxycontin use usually leads to. Ibogaine is needed to eliminate the addiction. I suggest antidepressants be started immediately after ibogaine therapy under the supervision of a physician."

Further, an author indicates "that Crohn's disease should not be an exclusion criteria as one patient diagnosed with Crohn's disease had the disease placed in remission after ibogaine therapy." While other authors have not had such experience it should be noted that an early report from Dutch Addict Self-Help concerning Hepatitis C being placed in remission resulted in most providers, including then, NDA International, Inc. agreeing to treat patients with HCV whose liver enzymes were not greater than 400% above normal. It must be remembered that we are discussing an experimental medical procedure should that definition be accepted and that medicine itself is diverse in its effects, expectations or adverse events.

A number of authors indicate nonfatal adverse medical events in patients with stomach ulcers. Ibogaine may cause pain and/or bleeding in these patients. Whether this is a matter of irritation to the stomach lining or a more systemic effect is unknown at this time thus, it is unknown whether rectal administration rather than oral administration would overcome this problem.

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TREATMENT REGIMEN AND DOSE

Anticipating that the subject and provider have reached this point in discussion and or treatment, the subject will have met all inclusion criteria and no exclusion criteria. This brings us to actual treatment requirements and dose.

1. The patient should be well rested.
2. All drugs that are not medically required and/or contraindicated should be stopped early enough to be cleared by the subject undergoing ibogaine administration.
3. In the treatment of opioid dependence, short acting opioid drugs should be stopped no less than eight hours before ibogaine administration. Methadone should be stopped no less than 24 hours prior to ibogaine administration.
4. The issue of sedation of the subject particularly in the treatment of opioid dependence is not uncommon. The question of whether sedation, post 30 hours should it be requested or required by the patient, would be beneficial or not to ibogaine therapy has not been answered. Some if not all providers feel that ibogaine effects would be best concluded without sedation. However, patient comfort is an issue and sedation may become a requirement in the treatment of any particular patient.

Ibogaine has been administered safely with various forms of sedation including benzodiazepines, barbiturates, melatonin, valerian and chamomile.

On an adjunct issue, one author comments, "benzodiazepines are useful before, during and/or after the ibogaine dose if there is anxiety. If there is considerable anxiety some days after detoxification buspirone is better because of its low liability for addiction."

5. A number of authors comment on the issue of hydration or in the inverse dehydration. "Post ibogaine the drinking of water is very important. Initiates are requested to drink at least 3 liters of water a day. This is not only for the purpose of avoiding dehydration but, as it is the feeling of this author that ibogaine loosens toxins in the body and, they are excreted during the initiation and afterwards. The only vehicle to accomplish this is pure water."

On an issue of safety, states an author, "I would also include avoiding dehydration. Many subjects don't feel like drinking for some time after ibogaine and if not reminded they would not drink a drop of water for more than 24 hours. This can lead to dehydration even without vomiting. With vomiting I would view the loss of liquids as threatening."

Continuing, another author states, "I have received patient reports that IV hydration is commonly used at the St. Kitts facility. This is not out of keeping with standardized procedures of hydrating patients undergoing surgery or chemotherapy."

6. Emesis or vomiting is a patient condition known to all ibogaine providers. Whether a provider believes there is benefit to vomiting as part of ibogaine therapy or ritual is moot if enough of the drug cannot be absorbed to allow the therapeutic experience. To that end various providers have indicated the use of substances as diverse as ginger tea, gravol/dramamine (dimenhydrinate), motillium (domperidone) and reglan (metaclopramide). This author participated in research involving all except ginger tea and upon reflection am uncertain if dimenhydrinate or domperidone had any effect above that of keeping the patient motionless. Metaclopramide 20 mg IV was the only medication that immediately stopped vomiting in ibogaine patients. No determination was made of whether oral metaclopramide administered prior to ibogaine would have as significant an effect as the IV administration of the drug. I anticipate this should be determined.

7. "As to dose," one author comments, "given the modest dose range given in the manual (and I agree a publicly presented manual should lend itself to caution), the 15 - 20 mg/kg of body weight will tend to leave 5 - 10% of the opiate withdrawal symptoms. I suggest a test dose of 2 mg/kg of weight be given with an antinauseant an hour before a dose of 13 - 16 mg/kg. The effect of the 2 mg/kg "test dose" will usually produce slight euphoria which lends to a person being more amiable to receive the next and largest dose. Whereas, years ago, during the first series of sessions, after giving the full amount of 18 - 22 mg/kg that followed the 1 mg/kg "test dose", we found that giving a smaller amount of 13 to 16 mg/kg allows for more comfort for a person who is obviously less traumatized by the intensity of the first stage and more open to receiving a booster of 6 - 8 mg/kg 5 to 8 hours later. On occasion, only when necessary, we

administer an additional booster of 3 - 4 mg/kg with 24 hours of the beginning of the session, usually during the early morning hours before sunrise. I have written only a synopsis here as there are reasons, exclusions, etc., every step of the way according to the psycho-physical reactions of the individual as the session progresses."

8. The use of a multi-dose regimen of ibogaine, over time, particularly for methadone, is in keeping with literature in the field (Kosten and Kleber, Am J Drug Alcohol Abuse 1984;10(2):249-66) indicating physical withdrawal signs to methadone may be precipitated as long as 14 days after the administration of methadone by a narcotic antagonist drug such as naltrexone.

Included herewith, is a report of a dose regimen used to treat a patient who had been receiving 300 mg of methadone per day, the highest dose of methadone dependence yet treated with ibogaine says one provider.

We have recently used the following regimen to clear a methadone dependent person who was taking 300 mg of methadone per day.

At 52 hours after the patient's last 300 mg. methadone dose, we gave him 5,200 mg Indra extract.

Over the next 72 hours, the patient has no physical withdrawal as per usual (in other words, no diarrhea, vomiting, sweating, running nose, pounding headache) but felt miserable.

72 hours after the first dose of Indra extract, we gave him 100 mg Ibogaine Hydrochloride.

96 hours after the first dose of Indra extract, we gave him 100 mg. Ibogaine hydrochloride.

120 hours after the first dose of Indra extract, we gave him 3,800 mg. Indra extract.

168 hours after the first dose of Indra extract, we gave him 100 mg. Ibo HCl.

192 hours after the first dose of Indra extract, we gave him 100 mg. Ibo HCl.

By his 11th day here (12 days from his last 300 mg. methadone dose), he was bright, sharp, lucid, no slurring, no signs of any methadone, no withdrawal or craving or discomfort of any kind. Patient said "I like the way I'm thinking now."

Patient ate little in the 12 days. Lost 25 pounds. Looks robust, healthy skin. "On methadone, I gained 110 pounds" he commented". The ibogaine is returning him to his regular body weight I feel.

"Something should be said about dose and product," states another author. "First, some new guides, new to the use of ibogaine, may be confused in dose distinctions between HCl and extract. It would be a very unpleasant death, I suppose, with 4 or more grams of ibogaine HCl on board. Second, in my opinion 29 mg/kg of HCl is too much. I experimented with dosages in the range of 13 to 22 mg/kg and came to the following conclusion - 15 mg/kg is for the first time the optimal dose. It is effective for withdrawal and craving and for the vast majority of patients is neither too weak or too strong. Then, from the second treatment on (which I prefer to administer not earlier than 3 or 4 weeks afterwards) the subject can easily cope with 20 mg/kg and does not feel it as stronger than the first treatment."

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PRODUCT IDENTITY

The proposal of discussion of ibogaine product identity particularly for the benefit of new providers and patients is certainly legitimate as three principal forms of ibogaine of diverse

purities are in use in ibogaine therapy. These substances may be, a highly purified form of ibogaine, an extract of *T. iboga*, that may be as low as 90% or as high as 99% in purity. Most examples of these products are 95% pure ibogaine. These products are available from commercial chemical manufacturers or by custom manufacturing by qualified chemists in university laboratories. Purified ibogaine may also be obtained by direct conversion from voacangine. This product when available had been assessed at 99.4% purity. The second principal form of ibogaine currently available is a crude total alkaloid extract and contains a reported 15% to 20% total alkaloids of which half is ibogaine. As the other iboga alkaloids contained in the total alkaloid products are active, this material should be viewed as having a potency of 15% to 20% ibogaine equivalency depending on source and batch. These total alkaloid extracts have been supplied by sources in Denmark and Canada. The third form of ibogaine material is the crude plant root bark. Depending on potency, this product may contain from 1% to 6% ibogaine. Most root bark will be in the 2% - 4% range. Any person taking ibogaine or providing ibogaine to another person should be certain of the identity of the substance as confusion of purified ibogaine and a less potent total alkaloid extract might cause a fatal reaction or not be sufficient as a dose to interrupt chemical dependence.

While the initial discovery and early research with ibogaine principally used single doses in the 15 mg/kg - 25 mg/kg range of ibogaine, the expanding base of data being presented by ibogaine providers throughout the world propose multiple dosing regimens. These dose regimens make use of purified ibogaine HCl, total extracts and root bark though principally, ibogaine HCl and total extracts except in the African religious model. Doses considered by a variety of providers to be full therapeutic doses may vary from 15 mg/kg - 25 mg/kg for ibogaine HCl and from 3 gram to 5 grams for total alkaloid extracts for the treatment of chemical dependence. For the purpose of this discussion a full therapeutic dose of ibogaine is one that will precipitate all three stages of ibogaine activity in most but, not all patients: 1) The waking dreamlike state, 2) the cognitive evaluation period and 3) residual stimulation eventually leading to sleep. Depending on circumstance and patient need, full therapeutic doses may be administered in a multidose paradigm a week to months apart.

Adjunct dose levels of ibogaine may be mediate or low. A mediate dose would be 300 mgs to 400 mgs of ibogaine HCl or possibly 1.5 to 2 grams of total extract while low doses may be in the range of 25mg to 50mg total dose range for ibogaine HCl and 100 mgs to 300 mgs of total alkaloid extracts. Mediate doses are generally used to boost a therapeutic dose should opiate withdrawal signs become evident or in the cases of some providers for a broader set of issues. Low dose regimens have been implemented for periods of ten to twenty days after recovery from a full therapeutic dose for antidepressant, antianxiety or antiwithdrawal applications. These regimens have been used in the treatment of both opiate and stimulant disorders in furtherance of the full therapeutic dose of ibogaine. It must be recognized that providing ibogaine is an art and a science and that ibogaine providers will use a multitude of doses individually determined on a patient by patient basis in accordance with the experience of the provider.

For additional information, comparative dose and strength tables from the chapter by James and Renate Fernandez found in Vol. 56 of The Alkaloids series published by Academic Press (2001) are shown below.

Alper et al.	
Ibogaine dose to facilitate personal growth and change:	10 mg/kg
Ibogaine single dose in self-help network for addiction interruption:	20 mg/kg
<i>Animal studies for neurotoxicity:</i>	
Alternate daily dose ibogaine over 60 days [no toxicity]:	10 mg/kg
Ibogaine dose associated with no evidence of toxicity [but decrease in drug self administration:	40 mg/kg
Ibogaine dose associated with cerebellar damage:	100 mg/kg

Lotsof (personal communication in preparation for ibogaine conference)	
Ibogaine dose causing modest psychoactivity with euphoria, altered perception of time:	90-120 mg
Amount of ibogaine ingested by adept that would allow remaining centered enough to assist in initiation ritual:	200 to 300 mg
Ratio of fresh root scraping to dry root bark:	15/1
Proportion of <i>iboga</i> alkaloids in dry root bark (50% ibogaine):	2 to 3%
Rounded teaspoon of root bark:	3 to 4 g
Amount <i>iboga</i> alkaloids in rounded teaspoon per above calculations:	60 to 120 mg
Fernandez	
Pick-up dose , <i>iboga</i> alkaloid content of 1 rounded teaspoon of dry root bark:	60 to 120 mg
Large dose for initiation into Bwiti, gradual intake of fresh root scrapings, maximal dose observed:	1000 g [one kilo]
Dose recalculated as dry scraping [1000/15]:	67 g
Content of <i>iboga</i> alkaloids of the above quantity of root scraping, assuming an average 2.5% <i>iboga</i> alkaloid content:	1.675 g
Total maximal Bwiti <i>iboga</i> alkaloid dose calculated per kilo of body weighty in small initiate weighing 50 kilos [hence a high estimate]:	33.5 mg/kg

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POST IBOGAINE THERAPY

There is no clarity that any form of adjunct therapy administered during the post ibogaine period following acute ibogaine effects is more efficacious than any other form of adjunct therapy in prolonging periods of abstinence and freedom from drug craving. This is also in keeping with the findings in chemical dependence treatment of non-ibogaine patients. It is the hope of the authors that findings of significance concerning efficacy or advantages of one form of therapeutic modality over another may be addressed in future revisions of the manual. Provider contributions are encouraged.

One author indicates, as for post-ibogaine therapy we have found that it is essential for addicts to quit smoking tobacco. Nicotine has proven to act on receptors that cocaine and other drugs also effect. Statistics show that 90% of addicts smoke and nicotine can cause craving for other drugs. Many patients find that cigarettes taste different after ibogaine and we encourage them to quit by using nicotine patches and Wellbutrin (bupropion HCl).

A second author adds, "With regard to the question of suitable post-ibogaine therapy, my opinion, from personal experience and reading Bwiti literature, is that bio-energetics or other body-based psychotherapies are most useful. The Bwiti dance constantly on iboga in the regular group sessions at the temple (not during the high dose "initiatory" session, you can't move as I'm sure you're aware!) and I'm sure this is for a reason."

"My personal opinion, based on my experience of doing ibogaine, doing quite a bit of therapy afterward, and observing others who've done ibogaine with or without therapy afterward, is that

there is sometimes a real problem with integrating the ibogaine experience properly and not simply at an ego-level. The tendency towards developing a 'need' for alternative belief systems to avoid bodily integration of the experience is, in my opinion, particularly marked in ibogaine users. (ie the individual NEEDS to believe something is true as opposed to being able to simply take or leave an idea)"

"Therefore body-based and emotional release therapies like primal, bio-energetics and encounter are probably highly synergistic with the ibogaine experience, in my opinion. My personal recommendation would be Humaniversity therapy, available at the Humaniversity up on the Dutch coast, and available to addicts as the Residential Addiction Foundation Program (RAF Program) lasting 3-6 months or longer."

Another author adds, "I constantly emphasize that to take full advantage of a session it is imperative to follow through with therapy. If the 12 step programs appeal to a person then, by all means incorporate the meetings into the post session program. A couple of ingredients apply specifically to people compelled to consume drugs. One, is they do not want to experience any level of pain, i.e. physical, emotional pain is to be avoided at any cost. The second insight is that a percentage somewhere in the 90's have experienced a deep level of physical and/or emotional abandonment from the same sex parent. Individual therapy, which necessitates finding a same sex therapist to establish the therapeutic relationship which includes transference of initial role model issues within the framework of the relationship is most healing so that by the time the metabolite washes out of the receptors from the session, the deep issues which created the addiction to begin with from the role model relationship in question has solidly begun to be actively addressed. This crucial type of therapy is, to say the least a challenge to create because of the threat it imposes to the very core ego structure. And so in the name of therapy most people will find a counselor who they are comfortable with and not at all intimidated by. This type of talk therapy will not be sufficient."

A fifth author comments, "It's frequent that addicted clients think that if they still feel some withdrawal effects or craving after more than 20 hours after ibogaine intake, then it didn't work out for them and they tend to search for a dose of their drug of choice. The treatment provider must be aware that ibogaine often needs some days to stabilize its effects and therefore should heighten his immunity toward the addict's heartbreaking performances."

"It is important to understand the differences between treating addiction as only a physiological medical condition and treating addiction with its related psychological and social issues. In spite of the fact that ibogaine is not far from being a miraculous treatment tool, the way it is generally used is highly ineffective and wastes ibogaine's potential. I am talking about overnight treatments that do not include an integrated treatment program. Ibogaine simply needs to be incorporated into already existing addiction treatment networks and then it will show its real potential. "

And, a sixth author: "Private therapy is somewhat hit and miss. There are brilliant practitioners out there but not many with any ibogaine experience (if any)." "... bodywork is extremely important." "So for people that are disillusioned by therapists and group counsellors various forms of bodywork can be extremely effective - acupuncture, rolfing, breathwork (rebirthing or Grofs), dance and movement therapy. Anything that reconnects you with the trauma lodged deep in your body. If you have been addicted for years the ibogaine may bring the reasons for the distress to the surface but that won't necessarily release them - especially if they are lodged deep - which is why the previously mentioned practices help."

"I would also suggest that a support group is extremely beneficial. Unfortunately no matter how much I tried I couldn't get the people that I had seen to form an ibogaine support group and I think this would really help. I have seen it help on the ibogaine list. People able to talk to each other about their experiences on line. Perhaps this is the only way to do it but it would be good for example to have a group... that met once a month to talk about things."

"To conclude, no three day recovery program in itself can correct years of substance abuse. It is therefore essential to arrange follow up care. The ibogaine experience itself leaves you open and enthusiastic about creating changes in your life. Post treatment bodywork/counselling is

essential, as it will help maintain this positive transformation and facilitate a deeper understanding and release of years of abuse."

While still another reflects, "I think it is important we not only reach for the most significant endpoint in offering ibogaine therapy but, view what we are doing from a harm reduction perspective and a pro-patient perspective in that anything that benefits the patients, short or long-term, should be viewed as a valuable outcome. I think it is universally accepted that multiple ibogaine treatments over time provide better results in most cases than a single administration. This is not to say that a single administration is not dramatic in its ability to interrupt an out of control addiction syndrome. I think it would be fortunate if ibogaine were a legally available medication through both social and private medical insurance programs. Availability coupled with normalization of addiction into mainstream medical treatment will offer the best outcome in our society which is medically directed. Under other circumstance, a religion would do just as well, and that is not to exclude the self-help group or association concept. From what I see of the suggestions of many of the authors, a belief system and the ability to take some action, to allow a sense of power and accomplishment are important."

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Invitation to Contribute

Many questions for which we seek answers remain: How do ibogaine providers best care for ibogaine patients? The primary authors continue to seek a consensus from ibogaine providers and patients as well as, others working in addiction medicine. Is a consensus possible? That remains to be seen but, with each revision of the manual we may come closer.

Submissions should be made to [Howard Lotsof](#). Accepted work will be incorporated into the next revision of this manual and the authors indicated as contributing authors to this manual or not, at their discretion. Revisions shall be made periodically.

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APPENDICES

NIDA DRAFT PROTOCOL

Rising Dose Tolerance Study using Single Administration to Assess Safety and Preliminary Efficacy of Ibogaine for the Treatment of Cocaine and/or Heroin Dependency

Developed/Issued

by

MDD/NIDA

(10/19/93)

[*Introduction Safety and Exclusion Criteria*](#)

[*Preclinical Studies*](#)

[*Exclusion Criteria*](#)

[*Psychological Assessments*](#)

[*Neurological Assessments*](#)

[*Opioid Withdrawal Assessments*](#)

*General Physical Condition
Assessments During Treatment*

Safety and Exclusion Criteria

[introductory statements]

To date, there is no published data from a controlled clinical trial that has assessed the safety of ibogaine in the treatment of drug addictions. Information from the anecdotal reports indicates there is a mild transient increase in blood pressure and a minimal effect on pulse and respiration.

To date, there is no published data from a controlled clinical trial that was conducted to assess the preliminary efficacy of ibogaine in the treatment of drug addictions. The initial observations of effects of ibogaine was a narrative account ([L.A.C., 1991](#)) of the results of taking ibogaine in the mid 1960s by seven heroin addicts, five of whom several days later reported no signs of withdrawal, abstinence, and no desire to take heroin.

Of the 7 clients in the mid-sixties, 6 received one treatment of ibogaine and the effects were that 2 resumed heroin use 24 hours later, one resumed heroin use 5.5 months later and the remaining 3 were drug-free 6 months after receiving ibogaine. One subject reported receiving ibogaine 5 times and reported abstinence from: heroin use for 3 years, cocaine use for 18 months and amphetamine use for 6 months.

Of the 18 clients in a contemporary group, 17 received one treatment of ibogaine and one received 2 treatments. After ibogaine, two clients continued to take heroin and one resumed heroin use 5 days later. Six subjects were drug-free from 2 weeks to 18 months, but contact was lost with them. Two subjects were heroin-free for six months and were awaiting retreatment with ibogaine. One subject was cocaine-free for 3.5 years. The remaining 5 subjects were drug-free for 2-10 months.

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Preclinical Studies on Ibogaine

Safety Issues

The most salient safety issue is contained in the findings of ([O'Hearn et al., 1993](#)) that when rats were administered high doses of ibogaine (100 mg/kg i.p.) glial cells in the cerebellum were activated, thereby suggestive of neuronal damage which the authors hypothesized were most likely the purkinje cells. [\[see additional documents #1 and #2\]](#)

Other safety issues about the effects of ibogaine are contained in the reports of: increased blood pressure and heart rate in conscious dogs and decreased blood pressure and pulse rate in anaesthetized dogs ([Gershon and Lang, 1962](#)), decreased blood glucose (ibogaine 20 mg/kg or 40 mg/kg) and increased blood glucose with higher doses in rats ([Dhahir, 1971](#)).

Safety Measures - Cerebellar Functioning

Prior preclinical studies indicated that the major safety issue with the administration of ibogaine is the remote possibility of lasting damage to the cerebellum, especially the purkinje cells. The repeated neurological assessments of cerebellar functioning in our subjects will consist of an extensive neurological examination that assesses most of the readily measurable dimensions of cerebellar functioning. The neurological examination was adapted from the application of

comprehensive preclinical work on the cerebellum that was summarized in a book by [\(Ito, 1984\)](#) to contemporary texts on neurological examinations [\(Kaufman, 1990; Scheinberg, 1981\)](#). The major neurological signs that indicate cerebellar damage are: dysmetria (inaccurate targeting of goal-directed behavior), delayed movement initiation and delayed reaction time, dysdiadochokinesia (inability to perform rapidly alternating repetitive tasks), hypotonia (reduced muscle tone), disturbances in gait and station, and intention tremor. The check-list for the Neurological Assessment Battery will consist of 12 behaviors that will be evaluated by the following discrete categories of impairment: none, mild, moderate and severe. In addition, while on inpatient status, PET scans will be conducted during the inpatient phase 3 days before and 3 days after the Ibogaine session and during the one-year follow-up assessment battery.

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Exclusion Criteria

1. Patients with a history of active neurological or psychiatric disorders, such as cerebellar dysfunction, psychosis, bipolar illness, major depression, organic brain disease or dementia, that require treatment or that would make study compliance difficult.
2. Patients who have a Beck Depression Inventory score greater than or equal to twenty-four.
3. Patients requiring concomitant medications that may interfere with a clinical trial or evaluation (e.g., anti-epileptic drugs, sedatives, hypnotics, antidepressants, neuroleptics, methadone, meperidine, etc.) [A significant number of patients treated in the last decade outside of this proposed research study have been dependent on methadone, meperidine or sedatives].
4. Patients with a history of sensitivity or adverse reactions to the treatment medication.
5. Patients with a history of significant heart disease or a history of myocardial infarction.
6. Patients with blood pressure above 170 mm Hg systolic/105 mm Hg diastolic or below 80 mm Hg systolic/60 mm Hg diastolic or a pulse greater than 120 beats per minute or less than 50 beats per minute.
7. Patients who have a history of hypertension uncontrolled by conventional medical therapy.
8. Patients who have received any investigational drug within 6 months prior to entering the study. [*The authors received a report of concurrent use of ibogaine and 5 methoxy di isopropyl tryptamine (5meo dipt) that precipitated a medical event of near fatal proportions requiring over a week of hospitalization. Additionally the patient was diabetic and did not monitor blood glucose levels.*]
9. Patients who have received any drug known to have a well-defined potential for toxicity to a major organ system within the month prior to entering the study.
10. Patients who have clinically significant laboratory values outside the limits thus specified by the investigators laboratories.
11. Patients who have any disease of the gastrointestinal system liver or kidneys, or abnormal condition which compromises a function of these systems and could result in a possibility of altered metabolism or excretion of the study medication will be excluded. As it is not possible to enumerate the many conditions that might impair absorption, metabolism or excretion, the investigator should be guided by evidence such as:
 - A. History of major gastrointestinal tract surgery (e.g., gastrectomy, gastrostomy, bowel resections., etc.) or a history or diagnosis of an active peptic ulcer or chronic

disease of the gastrointestinal tract, (e.g. ulcerative colitis, regional enteritis, Crohn's disease* or gastrointestinal bleeding).

B. Indication of impaired liver function.

C. Indication of impaired renal function.

12. Patients who test positive for HIV virus.

13. Patients with active tuberculosis.

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Psychological Assessments

1. Interviews

A. Addiction Severity Index (ASI)

B. Diagnostic Interview Scale (DIS)

2. Questionnaires

A. Visual Analogue Scale cocaine craving (VAS)

B. Beck Depression Inventory (BDI)

C. Minnesota Multiphasic Personality Inventory-2 (MMPI-2)*

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Neurological Assessments

1. Electroencephalography (EEG)

2. Neurological Assessment Battery

A. Coordination/tremor

a. Finger-to-nose

b. Finger-to-finger

c. Heel-to-shin

B. Coordination/tremor, Repeated rapid alteration tests

a. Palm/back hand slap knee

b. Prone/supine forearm

C. Coordination /ataxia

a. Heel-to-toe walking

b. Romberg test (feet together, eyes open/eyes closed)

D. Muscle tone/hypertonia

a. Resistance to stretch

E. Reflexes

- a. Acoustical startle
- b. Pupillary light reflex
- c. Vestibulo-ocular reflex

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Opioid Withdrawal Assessments*

- 1. Objective Opiate Withdrawal Scale (OOWS)*
- 2. Subjective Opiate Withdrawal Scale (SOWS)*

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General Physical Condition

- 1. History and Physical
- 2. Electrocardiogram (EKG)
- 3. Laboratory

Blood Work

- a. CBC DIFF
- b. AST ALT
- c. Hepatitis screen
- d. Thyroid panel
- e. SMA-18 profile
- f. CHEM-25

Urine

- a. Routine urine analysis
- b. Toxicology screen (positive for target drugs)
 - 1. cocaine
 - 2. morphine (heroin)
 - 3. cocaine
 - 4. ibogaine

Dermal Tuberculin (if positive or previously immunized, then chest x-ray)

Breathalyzer

Vital signs with weight

HIV test and counseling

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Support staff and design of environment

Generally, the session room should be pleasant and the social interactions with staff members supportive. Pastel-colored walls, comfortable hospital bed, soothing murals, paintings or pictures, a comfortable chair for the staff member or therapist to constantly observe the subject during the ibogaine experience. Dim lighting and quite setting. Dialogue should be initiated by the patient. Reduce the need for walking by having a patient lavatory nearby.

Within this context, allow the patient to sleep and rest peacefully ad lib. Otherwise, when the patient is in the talkative phase, the staff member should attentively and unobtrusively attend to but not initiate conversation.

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Assessments [during treatment]

Cardiovascular - Apply ambulatory pulse and blood pressure apparatus that is programmed to obtain and record digital quantities q 30 min for a 24 h period. Apply device just before dosing.

Neurological - Observe for the onset (that is time from the administration of ibogaine) for drug-related changes in neurological functioning (e.g., the onset of changes in speech patterns, nausea and vomiting)

Psychological - Observe and record what patients spontaneously say, Record the onset and duration of the somnolent phase.

Related Protocol Bibliography

Dhahir, **A comparative study of the toxicology of ibogaine and serotonin**. Doctoral Thesis. 1971. [return to chapter](#)

Gershon S., Lang W.J., A psycho-pharmacological study of some indole alkaloids. **Arc. Int. Pharmacodyn.** **85**, 31-62, 1962. [return to chapter](#)

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Kaufman, D.M. **Clinical neurology for psychiatrists (3rd Ed.)**. Philadelphia: W.B. Sanders Co., Pp 18-20, 1990. [return to chapter](#)

L.A.C. Can a psychedelic drug cure drug addiction? The ibogaine story. **Drugs, Toxic Chemicals and Health** **6**, 1-2, 1991. [return to chapter](#)

O'Hearn E., Long D.B., Molliver M.E. Ibogaine induces glial activation in parasagittal zones of the cerebellum. **Neuroreport**. **4**, 299-302, 1993. [return to chapter](#)

Scheinberg P. **Modern practical neurology; An introduction to diagnosis and management in common neurologic disorders (2nd Ed)**. New York: Raven Press 1981. [return to chapter](#)

*****End NIDA Protocol Selections*****

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Additional Documents

1. An evaluation of **ibogaine neurotoxicity**, including abstracts of relevant papers. [Return to chapter](#)
2. Daniel Luciano MD **describes neurological observations** of treatment with ibogaine. [Return to chapter](#)
3. What's in a **blood test? (SMA-20)**. You are about to find out. [Return to chapter](#)
4. A good place to learn the **terms used in blood test reports**, their meaning and the significance to health related issues. [Return to chapter](#)
5. A CBC or **complete blood count** along with a **differential** that indicates the breakdown in the types of white blood cells offers a comprehensive view of blood chemistry in conjunction with the SMA-20. [Return to chapter](#)
6. A general review of cardiovascular disorders can be found at **The Open Directory Project** and at **The Medical Center Online**. The topic is also well covered in **Section 16 of the Merck Manual** [Return to chapter](#)
7. Everything you want to know about **electrocardiograms** if you could think of the questions. [Return to chapter](#)
8. This early report, **Reflections on an Ibogaine Experience**, provides an excellent treatment overview that includes concurrent ibogaine/heroin use by the patient. The survival of this patient should not be taken to indicate the survival of other patients under similar circumstance. [Return to chapter](#)
9. A copy of the **Beck Depression Inventory** is available as an FDA document. This page automatically downloads the pdf file of the beck depression inventory to your computer. PDF files require adobe reader programs that are available at no cost **from Adobe** [return to chapter](#)
10. The Minnesota Multiphasic Personality Inventory **MMPI-2** may prove a valuable tool in assessing pre and post-treatment behavior of patients. [Return to chapter](#)
11. The Diagnostic and Statistical Manual of Mental Disorders, 4th. Edition, better known as the **DSM IV**, offers detailed descriptions of broad ranging psychiatric disorders. [Return to chapter](#)
12. Treatment of Acute **Opioid Withdrawal** with Ibogaine. Alper et al.'s review article of ibogaine effects on opioid withdrawal signs of subjects from the United States, The Netherlands and Panama over a period of three decades is now available as a **downloadable PDF file**. In order to read a PDF file you will require an adobe reader program **from Adobe**. [Return to chapter](#)
13. The early paper (1995) **Ibogaine in the Treatment of Narcotic Withdrawal** by Lotsof, Della Sera and Kaplan provides useful information on the comparative effects of ibogaine and narcotic withdrawal. [Return to chapter](#)
14. Ibogaine in the Treatment of Chemical Dependence Disorders: **Clinical Perspectives** offers an overall view of ibogaine therapy and what may be anticipated during treatment. [Return to chapter](#)

15. Frenken, an early ibogaine researcher provides her views on ibogaine therapy in [An Ibogaine Treatment Protocol](#) providing a view of the Dutch ibogaine self-help movement. [Return to chapter](#)
16. Nick Sandberg presents a thorough review of ibogaine safety, effects and history in his original work [Introduction to Ibogaine](#) [return to chapter](#)
17. A good place to begin to gain an understanding of a structured report form. [Guidelines for psychiatric evaluations of Adults.](#) [return to chapter](#)
18. [Catalogue of diagnostic questionnaires.](#) [return to chapter](#)
19. [Brief Psychiatric Rating Scale.](#) [return to chapter](#)
20. [The Sexual Inequality of Drug Metabolism.](#) *The Scientist* 16[6]:29. [return to chapter](#)
21. [Notes to Treatment Providers](#) by H. Wells gives a view of ibogaine treatment issues in the United Kingdom. [return to chapter](#)
22. Always of value, [a medical encyclopedia.](#) [return to chapter](#)
23. "Merck & Co., Inc., is proud to introduce [The Merck Manual of Medical Information--Home Edition.](#) This all-new publication is based on The [Merck Manual of Diagnosis and Therapy, Centennial Edition](#) , commonly referred to as The Merck Manual, the textbook of medicine most widely used by health care professionals in the U.S. and worldwide. The Home Edition transforms the language of the professionals' version into commonly used English while retaining the vital information about diseases, diagnosis, prevention, and treatment." The reader should review both volumes to determine which best meets your needs. "The Merck Manual of Medical Information--Home Edition, like all the Merck manuals and The Merck Index, is published by Merck & Co., Inc., on a not-for-profit basis. Copyright © 1995-2001 Merck & Co., Inc., Whitehouse Station, NJ, USA. All rights reserved." [return to chapter](#)
24. [How to Safely Use Ibogaine](#), a public document of the Iboga Foundation, a not-for-profit group in Slovenia approaching ibogaine use from a religious perspective.

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